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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,086	07/16/2003	Douglas J. Hauck	158390-0005	1850

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EXAMINER

KRASS, FREDERICK F

ART UNIT PAPER NUMBER

1614

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,086	HAUCK, DOUGLAS J.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 1-30 and 38-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>15 March 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

Restriction/Election of Species Requirement

Applicant's election of the following in the reply filed 03 November 2005 is acknowledged:

- 1) Group I, claims 1-66, per the restriction requirement; and
- 2) the ultimate species "crowns", "coating methods" and "flavorings", respectively, per the election of species requirement.

Because applicant did not distinctly and specifically point out the supposed errors in either the restriction or election of species requirement, these elections have been treated as elections without traverse (MPEP § 818.03(a)).

Claims 1-30 and 38-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim.

Claims 67-69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Duplicate Claim Warning

Applicant is advised that should claim 32 be found allowable, claim 35 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two

Art Unit: 1614

claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The "hydrogel" of claim 32 does not appear to be clearly delineated from the "low viscosity hydrogel" of claim 35, since claim 31 (from which both depend) already recites a "low viscosity" composition.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The term "low viscosity" in claims 31 and 35 is a relative term which renders the claim indefinite. The term "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

2) The term "desired" in claim 31 is a relative term which renders the claim indefinite. The term "desired" is not defined by the claim, the specification does not

Art Unit: 1614

provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Specifically, it does not appear possible to differentiate a medicament *per se* from a "desired" medicament. Since the term "desired" is not necessary to an understanding of the claimed subject matter, the examiner recommends deleting same in order to obviate this ground of rejection.

3) Claim 31, last line, the term "user" is unclear in meaning, insofar as no particular use is claimed. Again, since the phrase "of a user" is not necessary to an understanding of the claimed subject matter, the examiner recommends deleting it.

4) In claim 34, there is no antecedent basis for any of the species recited at the second line thereof. None of hydroxypropyl-cellulose, carboxy-methyl cellulose, or hydroxypropylcellulose is a hydroxylalkyl methyl cellulose as recited in claim 33.

5) Claim 36, third line, the scope of the phrase "compositions to improve oral health" is unclear. The specification fails to provide any definitional guidance; what is "improved" to one person may not be to another.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 31-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaffar et al (USP 5,575,652).

The prior art discloses oral gel compositions containing antimicrobial agents such as triclosan for coating teeth and gums, particularly in people having dental implants. Useful gel compositions include those made using hydroxyethylcellulose, hydroxypropylmethylcellulose, or carboxymethylcellulose (i.e., hydrogels: see col. 11, lines 60-67). The gels also contain flavoring oils (col. 14, lines 31-34). Insofar as can be determined given the lack of guidance provided by the instant specification, these are “low viscosity” gels since they are easily administered from a syringe and spread on the dental surface. Moreover, they appear to be “slowly releasing” (as defined at paragraph [0023] of the instant specification) since they are retained, and remain active, on the dental surface for extended periods of time such that they need be administered only once, or at most a few times, a day. See, for example, col. 14, lines 7-17.

Art Unit: 1614

2) Claims 31, 32, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Linden (USP 5,915,969).

The prior art discloses hydrogels for treating dental hypersensitivity (see, for example, the passage bridging col. 1, line 64 to col. 2, line 7). Again, insofar as can be determined given the lack of guidance provided by the instant specification, these are “low viscosity” gels since they are sufficiently workable to coat the tooth surface (col. 10, lines 66 and 67). Moreover, they appear to “slowly releasing” (as defined at paragraph [0023] of the instant specification) since prior art hydrogels containing active ingredients such as the antimicrobial chlorhexidine (col. 10, lines 52-58) are retained, and remain active, for extended periods of time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1614

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Fred Krass', is written below the printed name.